3.3 INSTITUTIONAL BIOSAFETY COMMITTEE

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3.4 ROLES AND RESPONSIBILITIES

Everyone at the University is responsible for maintaining a safe and compliant environment. Some of the roles and responsibilities regarding biosafety are listed below.

3.4.1 Principal Investigator (PI)

PIs are responsible for implementing applicable biosafety procedures and practices in their laboratories. They must ensure that the appropriate equipment and facilities are available for laboratory staff members and that they are used properly. They must also arrange for appropriate employee training regarding the safe use of potentially hazardous biological agents and require that individuals handling BBPs receive the annual training mandated by OSHA. Each PI must be aware of the potential adverse health effects of the biological materials used in his or her laboratory, the appropriate biosafety level, and any other pertinent factors that will ensure the safety of laboratory staff members and the surrounding community.

In addition to the responsibilities of the PI above, when research involves the use of rDNA, the PI agrees to abide by the NIH Guidelines. Under the NIH Guidelines, the PI has a number of specific responsibilities. In particular, the Principal Investigator must (among other tasks):

- Ensure that no research is conducted with regulated biological materials prior to approval by the IBC.
- Report any significant problems, violations of the NIH Guidelines, or any research-related accidents, illnesses, or potential exposures to BSO at (202) 806-9710.
- Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents. This instruction should be specific to the agents and materials used in the research project.
- Make protocols describing the potential biohazards and safety precautions associated with the agents to be used available to laboratory staff.

Additional responsibilities of the PI when working with rDNA are located in the NIH Guidelines (http://oba.od.nih.gov/rdna/nih_guidelines_oba.html). One PI's failure to comply with the NIH Guidelines could affect all NIH-funded projects at the University; therefore, compliance is absolutely mandatory.

3.4.2 Laboratory Staff and Student Responsibilities

Laboratory staff and students are responsible for following the University health and safety policies and the procedures and instructions from their PIs/Instructors. They need to comply with the NIH, CDC and OSHA regulations, use safe laboratory practices, and inform the PI, laboratory supervisor, or regarding any potentially hazardous situations or conditions.

3.4.3 Biosafety Officer

Responsibilities of Biosafety Officer include but not limited to:

- Developing, implementing and coordinating biological safety program for the University.
- Reviewing protocols involving biological materials and recombinant DNA and potential biohazards.
- Reviewing selected agents transfer to and from the University (i.e., Material Transfer Agreement (MTA)).
- Acting as resources for the University on various regulations and guidelines pertaining to the use, handling and disposal of potential biohazards and recombinant DNA.
- Inspecting research and teaching facilities for compliance with regulations involving the use, handling and disposal of potential biohazards and recombinant DNA.

3.5 RISK ASSESSMENT

In order to determine which practices and procedures are required when working with biological materials, a risk assessment should be conducted. At a minimum, the risk assessment should include the following:

- Pathogenicity of the biological material and infectious dose
- Potential outcome of an exposure
- Natural route of exposure
- Other routes of exposure (parenteral, airborne, ingestion, etc.)